Docket No.: 1268-083A

PATENT # D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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EXPEDITED PROCEDURE

RESPONSE UNDER 37 CFR 1.116

Shalom LEVI et al.

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U.S. Patent Application No. 10/086,727

Group Art Unit: 1615 Confirmation No. 2222

Filed: March 4, 2002

Examiner: S. Tran

For: COMPOSITIONS FOR ELIMINATING HUMAN AND ANIMAL EXCREMENT

SMELLS

DECLARATION

Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

- I, Moshe Levy of 42 Weizmann St. Rehovot, Israel, an Israeli citizen declare hereinafter in writing as follows:
 - 1. I am Professor Emeritus at the Weizmann Institute of Science in Rehovot Israel.
- 2. I enclose as Annex "A" my Curriculum Vitae, and as Annex "B" my list of publications.
 - 3. This Declaration is given in support of U.S. patent application 10/086,727.
- **4.** For the purpose of this Declaration I have read and understand the following documents:
 - (a) The text of said U.S. 10/086,727 (I will refer to it in the following as: "The Application").
 - (b) The Office Action of May 20, 2003.
 - (c) The text of the proposed new amended main claim, which I have been advised, will be submitted within the framework of the Examination of this application;
 - (d) U.S. 4,909,986, Kabayashi et al.; U.S. 4,839,089, Shimezu et al.; and U.S. 5,882,638, Dodd et al.

5. When reading the text of the Application, together with the proposed claims, I understand that the present application is directed to a deodorizing composition which has the following properties:

- (a) It essentially consists of (claim 1) or comprises (claim 21) acidic agents;
- (b) It essentially consists of (claim 1) or comprises (claim 21) a unique group of water soluble polymers, which are characterized by the following:
- (b1) They, due to their chemical nature and their quantity in the final composition, form upon drying a thin film barrier that blocks gases emissions from manure;
 - (b2) They are biologically degradable, non toxic and ecologically safe;
- (b3) They have a concentration range of more than 0.1% in the composition.
- 6. I will now turn to Kabayashi *et al.* and compare each of the above elements of the polymers with Kabayashi *et al.*:

6.1 Water soluble polymers - overview

Water soluble polymers constitute a huge family of polymers which are characterized in that they can be dissolved in water. The present invention is directed to a specific sub-species of this huge family. The polymers of this sub-species are characterized in that they are capable of forming a thin film barrier; in that they are biodegradable, non-toxic and ecologically safe. Kabayashi *et al.* is directed to a <u>completely different, non-overlapping</u> sub-species. Kayabashi's water soluble polymers are **not capable** of forming a thin film barrier, are **not biodegradable**, are **toxic and are ecologically unsafe**, and are given concentrations that are orders of magnitude lower than in the present invention. Therefore they cannot form a continuous film that has any significant barrier effect to diffusion of malodorous compounds.

6.2 Water soluble polymers capable of forming a thin film barrier:

1. According to my understanding, the essence of the invention resides in the fact that the water soluble polymer can form, upon drying, a thin film barrier over excrement of human or animal, so that gases emission from said excrement is effectively blocked and this waste (for example produced by pigs, cattle, dogs, etc.) can easily be handled, for example, picked up and disposed without becoming disintegrated and while minimizing malodors emanating from the waste. Again and again throughout the specification of the Application, as well as in the amended claim, it is emphasized that the formation, upon drying, of a thin film barrier is the crucial and is the essence of the invention. Out of the huge family of water soluble polymers only polymers which are capable of forming a thin film barrier were chosen.

It should be emphasized that not all water soluble polymers are polymer barriers. Out of the huge family of water soluble polymers only polymers which are capable of forming a thin film barrier were chosen. This sub family is named Barrier Polymers (appears as a separate article in the Encyclopedia of Chemical Technology, KIRK-OTHMER, Third Edition, Volume 3, p.480-502), *See Annex D*.

Quotes from the Encyclopedia:

- 2. "This article deals with recently developed polymers exhibiting low permeability. These materials are generally referred to as barrier polymers".
- 3. "There are **certain molecular structures** that lead to good barrier properties in polymers"
- 4. "The permeability rate for gases or liquids is, therefore a function of many parameters. These are discussed below in greater detail, using oxygen as an example permeating gas."

Major parameters that are discussed are effect of functional groups, effect of crystallinity and effect of orientation.

From this article one can easily conclude that not all water soluble polymers are polymer barriers.

Contrary to the present application, the Kabayashi *et al.* polymers are **incapable** of forming film barriers and were not aimed to do so, as emphasized in the text of Kabayashi itself. The deodorizing effect of the Kabayashi polymers is due to their <u>flocculating effect</u>, which means that these polymers cause the odorous producing particles to collect into lumps or tufts consisting of flakes, and it is clear from the term "*flocculating*" (corresponding to flakes, tufts, aggregates, etc.,) that the polymers <u>never produce film barriers</u>.

For example, on Kabayashi, column 10, lines 26-31, it is stated: "The water soluble organic polymers used in the deodorant of this invention show a considerable removing effect on malodorous components such as a wider range of toxic gasses and offensive odors. This effect is considered to be due to the physical flocculating effect rather than to a chemical reaction. When the water soluble organic polymers are atomized into toxic gases or malodorous gases or as impregnated or included into substrates, they are contacted with such gasses, they efficiently capture the malodorous components physically". Again on column 10, it is stated that the sole purpose of the water soluble polymers is to physically capture the malodors while the other additives have the chemical effect (column 10, lines 42-46).

At the sentence abridging column 10 and 11 it is explicitly stated that: "The present inventors have confirmed from many examples that the efficiency of capturing malodorous components depends 60-80% upon physical capturing by flocculation of water soluble organic polymers and 20-40% upon chemical capturing by the additive". Reading this explicit indication of

4

the mechanism of action, it is clear to me that Kabayashi *et al.* sub-species of water soluble polymer is completely distinct from those of the present invention in that they <u>cannot form films</u>, <u>but rather</u> they form aggregates by a flocculating mechanism.

6.3 Concentration:

The concentration of the polymers in this Application is more than 0.1% of the composition. The concentration of the polymer at Kabayashi *et al.* is from 0.0005% to 0.05% as emphasized by the main claim (equal to 0.05-50 ppm), which is lower than the minimal range of the polymers according to the amended claim 1, from about <u>four orders of magnitude</u> to about one order of magnitude. The sole example of the Kabayashi patent where higher concentrations of amphoteric polymer is used (Example 54, column 23, line 61), these high concentrations are **not** used to prepare the final deodorant composition of Kabayashi *et al.*, but rather are merely used in **an examination procedure** wherein the active materials are concentrated to levels beyond those that will actually be used in the final products, in order to detect trace amounts of dangerous substances such as formaldehyde, acrylamide, demethylamide, etc.

It is clear that as the amounts of active polymers in the final deodorizing solution of Kabayashi *et al.* are extremely low, (0.0005% - 0.05%) that it was impossible to detect these possibly dangerous substances (such as formaldehyde) in their actual final product, so that in Example 54 they performed the well known manipulation of concentrating the substances beyond the concentration that will actually be used, merely to test for trace amounts of hazardous materials.

6.4 Biodegradable:

While the polymers of the present invention are designed to be biodegradable, as defined in the amended claim 1, the polymers of Kabayashi *et al.* goes to great length to avoid biodegradation as evident, for example, from column 9, lines 52-55 which reads: "It is very important to prevent biodegradation of the polymer and to take measurs so as to maintain the level of the molecular

weight of the polymer. For this purpose, it is desirable to sterilize water for dilution by boiling and the like and to reduce the level of the dissolved oxygen preferably to zero; preferably, a preservative or antiseptic is added to the diluting water ... ". As can be seen, Kabayashi explicitly points away from using biodegradable polymers of the present Application in that it emphasizes, and puts great effort in components so that the polymer of this patent would not be biodegradable, while in the present Application the case is exactly the opposite, and from the amended set of claims it is clear that the polymers **must be** biodegradable since in the present invention it is clear that the environmental concerns are important.

6.5 *Non-toxic and ecologically safe:*

It is very well known that nitrogen containing compounds, phosphates containing compounds, and sulfur containing compounds, when accumulated in the environment are sources of air and water pollutants: ammonia(air and atmosphere) and nitrate(water table), phosphate(lakes and rivers) and sulfate(soil and water table). Furthermore, in the Background of the present invention on page 1, paragraph [0002], it is stated that "in particular that they do not contribute to adding nitrates or phosphates to the water reservoir".

Docket No.: 1268-083A

Application No.: 10/086,727

Kabayashi *et al's* compounds are all toxic and are all ecologically unsafe, since they contain either an ammonium, phosphate or sulfur groups as evident by Claim 1 which recited the following compounds:

- (a) <u>Ammonium groups</u>: ammonium salt of carboxylic acid group, ammonium/alkali metal mixed salts of carboxylic acid, alkanolamine salts of carboxylic acid group, ammonium salts, alkanolamine salts, and alkali metal/ ammonium/alkanolamine mixed salts, cationic groups (being amine/NH₂), quaternized ammonium group.
 - (b) <u>Sulfur group</u>: sulfoalkyl groups, sulphonic acid group.
- (c) <u>Phosphur group</u>: phosphoric acid group, phosphonic acid group and their alkali metal salts.

As can be seen, all the specific components in the main claim of Kabayashi *et al.* are toxic, and ecologically unsafe, again pointing away from the amended main claim of the present application, which emphasized the non-toxicity and environmentally friendly of the components.

7. U.S. 4,839,089, Shimizu *et al.* seems to me a completely non-related application, as it concerns production of liquid soap from waste cooking oil, and is not concerned at all with deodorizing compositions in general, and more specifically water soluble film forming deodorizing compositions.

I understand from the Office Action that the sole reason for bringing this publication during the examination of the present application is the use of "perfume based and vegetable essences for masking oil odors such as lemonin...", but as I understand it, the fragrance containing essence is not the main issue of the present Application, but merely an additional optional feature, and therefore this publication does not seem to me relevant to the essence of the present application.

7

- 8. U.S. 5,882,638— Dodd *et al.* is again a teaching that completely points away from the present application. As emphasized again and again in my Declaration, the present Application concerns a composition which form a film barrier over the substance on which they are applied. Dodd *et al.* concerns a completely different composition that should be applied on human skin. It is of course crucial that compositions applied to the skin do not form, upon drying, a film over the skin, since this would prevent gas exchange and perspiration from the skin which is very dangerous. The composition of Dodd *et al.* contains water soluble cylcodextrine, which is **not a polymer at all.** I enclose as Annex "C" indicating that cyclodextrines are crystalline, water soluble, cyclic non-reducing oligosaccharides built up from six, seven or eight glucopyronose units. These are clearly not polymers, and clearly these do not form a film over the skin (which would be a thing to be avoided) and therefore I cannot see the relevancy of this publication alone or in any combination with another publication to the present case.
- 9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that willful false statements may jeopardize the validity of the Application, any patent issuing thereof, or any patent to which this verified statement is directed.

Moshe Levy

Executed on this _____ day of September, 2003.

Annex A

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Curriculum Vitae

1952 M.Sc. Hebrew University, Jerusalem.

1955 Ph.D. State University of New York, Syracuse N.Y. U.S.A.

1955 Post-doctorate Fellow, S.U.N.Y. Syracuse N.Y.

1956 Post-doctorate Fellow, Rutgers Univ., New Brunswick N.J.

1957-60 Lecturer, Physical Chemistry Department, Technion, Haifa.

1961 Research Associate, S.U.N.Y. Syracuse N.Y.

1962- Weizmann Institute of Science, Rehovot.

1968/69 Visiting Scientist, Research Center, Xerox Corporation, Rochester N.Y.

1972-74 Visiting Professor, Casali Institute of Applied Chemistry, Hebrew University, Jerusalem (part time).

1975/76 Visiting Scientist, Research Center, Xerox Corporation, Rochester N.Y.

1977-83 Head, Plastics Research Department, Weizmann Institute.

1979 Visiting Professor, Material Science Department, University of Florida, Gainesville FL.

1980 Visiting Scientist, Gulf South Research Institute New Orleans LA.

1984 Visiting Professor, University of Minnesota Minneapolis MN.

1985/6 Visiting Scientist, DuPont Central Research Department, Wilmington DE.

1988/9 Visiting Scientist, DuPont Central Research Department, Wilmington DE.

1992 Visiting Professor, Material Science Department, University of Florida, Gainesville FL.

1993 - Professor Emeritus.

1993/5 President, Israel Polymer and Plastics Society.

1998 - Editor of the Bulletin of the Israel Chemical Society - "Chemistry in Israel".

Areas of Research:

Polymers, Biomedical Research, Kinetics and Chemical Processes, Catalysis, Oil Shales, Solar Energy.

150 publications and patents.

Annex B

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Annex C

α-Cyclodextrin hydrate

Schardinger a-dextrin]

 $C_{39}H_{50}O_{30}$.x $H_{2}O$ FW 972.86 (anhyd) [10016-20-3] mp ca 278°(dec) $[\alpha/E^{0}$ +136±3° (c=10 in water)

RTECS GU2292000 EINECS 233-007-4 TSCA Fieser 9,129

Werck 12,2787 BRN 4227442

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R:36

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Annex C

480 BARRIER POLYMERS

BARRIER POLYMERS

This article deals with recently developed polymers exhibiting low permeability. These materials are generally referred to as barrier polymers (see also Packaging materials).

Factors Affecting Barrier Properties

The general theory of permeation of a gas or liquid through a polymer matrix states that the permeation rate is the product of a diffusion term and a solubility constant of the gas-liquid in the polymer matrix, each of which is often independent of the other. The process of permeation through a polymeric barrier involves four steps: absorption of the permeating species into the polymer wall; solubility in the polymer matrix; diffusion through the wall along a concentration gradient; and desorption from the outer wall.

There are certain molecular structures that lead to good barrier properties in polymers. A practical problem, however, is that the property that might result in a good gas barrier very often also results in a poor water barrier. Polarity is a case in point. Highly polar polymers such as those containing many hydroxyl groups [poly(vinyl alcohol) or cellophane] are excellent gas barriers but also among the poorest water barriers. In addition, they become poor gas barriers when plasticized by water. Conversely, very nonpolar hydrocarbon polymers such as polyethylene have excellent water barrier properties and poor gas barrier properties. In order to be a truly good barrier polymer the material must have: some degree of polarity such as contributed by the nitrile, ester, chlorine, fluorine, or acrylic functional groups; high chain stiffness; inertness; close chain-to-chain packing by symmetry, order, crystallinity, or orientation; some bonding or attraction between chains; high glass transition temperature (T_{ℓ}) .

The permeability rate for gases or liquids is, therefore, a function of many parameters. These are discussed below in greater detail, using oxygen as an example of the permeating gas.

Effect of Functional Groups. It can be seen from Table 1 that oxygen permeation varies widely with the nature of the substituent on the polymer backbone. It is highest for polyethylene and polypropylene and lowest for poly(vinyl alcohol) and polyacrylonitrile.

Effect of Packing. High-density polyethylene, having a simple molecular structure leading to good packing, has an oxygen permeation almost one-fortieth that of poly(4-methyl-1-pentene) which has poor molecular packing characteristics. Table 2 shows these comparisons.

Effect of Crystallinity. If a polymer can exist in more than one state of crystallinity, it will be the better barrier in the more crystalline form, since crystallites are generally impermeable. The data shown in Table 3 compare the oxygen permeability of polyolefins and nylon-6,6 with various degrees of crystallinity.

Effect of Orientation. The effects of molecular orientation on gas permeation vary quite widely depending on the particular polymer. In general, orientation decreases permeation by 10–15% depending on the type of polymer and the degree of orientation, but in some cases reductions are greater than 50%. In Table 4, four examples are given of the effect of orientation on oxygen permeability.

Vol. 3

Table 1.

-OH -CN -Cl -F

CHa
—phen:
—11

At 23

... 30

Table 2.

Polymer high-der polyproj

po)y(4-a

" At 23"

Table 3.

Polymer rubber,

low-dens high-des nylon-6, nylon-6.

4 At 23°

Eff or decr the pol to poly in cond